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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/150,813	09/11/1998	DAVID J. GRAINGER	295.027US1	6933

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EXAMINER	
MURPHY, JOSEPH F	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/150,813	GRAINGER ET AL.	
	Examiner	Art Unit	
	Joseph F Murphy	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *63-65,67-69,71-73 and 75-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *77 and 83-87* is/are allowed.

6)☒ Claim(s) *63-65, 67-69, 71-73, 75-76, 78-82, 88-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Claims 63-65, 67-69, 71-73, 75-92 are pending and under consideration.

Response to Arguments and Amendment

Applicant's arguments filed 3/22/2004 have been fully considered but they are persuasive in part, for the reasons set forth below.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 63-65, 67-69, 71-73, 75-83 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting leukocyte migration by administration to a mammal an effective amount of SEQ ID NO: 1, 7, 14, 38, 40-44, 65-68, 72-74, and the reverse D sequences listed in claim 67, does not reasonably provide enablement for a method of preventing or inhibiting an indication associated with leukocyte recruitment or migration by administration of the peptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The rejection of record set forth that the claims are directed to the prevention or inhibition of indications associated with either leukocyte migration or recruitment. The Specification teaches that chemokines are associated with the inflammatory response (page 30,

lines 26-29), and discloses examples of the effect of the peptide 3 sequence on the inhibition of THP-1 cell migration (page 134, Table 4). The Specification further discloses indications that are associated with leukocyte migration or recruitment on pages 47-49 of the Specification.

The first issue is whether the disclosure is enabling for prevention of indications associated with leukocyte migration or recruitment. In order for one of skill in the art to practice this method, they would have to know that the mammal to which this peptidic compound would be administered would develop the indication. In the Declaration submitted 9/23/2003, Applicant cites evidence that the peptidic compounds can be administered prophylatically, and points to Example 9 of the Specification wherein mice are pretreated with the peptide 3 compounds before administration of LPS, and the migration of THP-1 cells is thereby inhibited. Applicant further argues that several references were submitted which indicate that the risk factors are known for several of the listed indications, including IDDM, atopic dermatitis nephritis and optic neuritis, and argues that thus the scope of the claims is enabled. However, several of the indications that are encompassed by the claims do not have risk factors that are well known, e.g. autoimmune disorders, Crohn's disease, multiple sclerosis, Alzheimer's disease. Other indications listed are congenital, such as cystic fibrosis. So it would be beyond the realm of ordinary experimentation for one of skill in the art to practice the method in its full scope, since the skilled artisan would need to determine with particularity the definitive risk factors for development of all these indications, and then administer the compounds. In addition, it is not clear how one of skill in the art could use the peptide 3 compounds to prevent a congenital disorder, such as CF, thus the claims as written are not enabled for prevention.

The second issue is whether the disclosure is enabling for inhibition of indications by administration of the peptidic compounds. The specification discloses several examples of methods of administration, including a rat dermal inflammation model, a mouse asthma model, and a mouse endotoxemia model. However, these do not serve as models for the entire range of indications set forth on pages 47-49 of the Specification. Furthermore, since the therapeutic indices of biopharmaceutical drugs can be species- and model-dependent, it is not clear that reliance on the mouse and rat in vitro and in vivo experimental data accurately reflects the relative efficacy of the claimed peptidic compound therapeutic strategy. Pharmaceutical therapies are unpredictable for the following reasons; (1) the protein may be inactivated before producing an effect, i.e. such as proteolytic degradation, immunological inactivation or due to an inherently short half-life of the protein; (2) the protein may not reach the target area because, i.e. the protein may not be able to cross the mucosal or blood-brain barrier, or the protein may be adsorbed by fluids, cells and tissues where the protein has no effect; and (3) other functional properties, known or unknown, may make the protein unsuitable for in vivo therapeutic use, i.e. such as adverse side effects prohibitive to the use of such treatment. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992). The CAFC decision (Genentech Inc. v. Novo Nordisk, 42 USPQ2d 1001, 1997) expressly states that:

> "When there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

Since the Specification does not set forth the conditions under which the claimed method can be carried out, given the range of indications encompassed by the claims, the claims as written are not enabled.

Conclusion

Claims 77, 83-87 are allowable.

Claims 63-65, 67-69, 71-73, 75-76, 78-82, 88-92 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
May 27, 2004